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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,924	02/12/2002	Rebecca Redman	INBI-009/01US	1990

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EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/075,924	Applicant(s) REDMAN ET AL.	
	Examiner Khatol S Shahnan-Shah	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 and 6*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicants' amendment of 12/04/2002 in regard to sequence listing is acknowledged.

2. Applicants' response to notice to comply to sequence rules of 12/04/2002 and 12/27/2002 is acknowledged. The CRF is good technically and has been entered in the database.

Information Disclosure Statement

3. Applicants' Information Disclosure Statements of 9/30/2002 and 10/23/2002, papers # 5 and 6 are acknowledged. The references have been considered by the Examiner. See attached forms PTO 1449.

Drawings

4. The drawings were received on February 12/2002. These drawings are accepted by the examiner.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4-8 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a 0.3 wt% composition of IB-367, does not reasonably provide enablement for 0.03 wt% composition of IB-367. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/or use the invention commensurate in scope with these claims.

Claims 4 and 19 recites a composition of about 0.03 wt% to about 0. 3 wt% of IB-367. The specification is only enabled for a 0.3 wt% composition of IB-367 (see page 8 composition and

page 11 experimental protocol). The instant specification invites the skilled artisan to experiment. The factors, which must be considered in determining undue experimentation, are set forth in In re Wands USPQ2d 14000. The factors include

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art and the
7) breath of the claims.

With regard to factors one and two cited above the quantity of experimentation needed to determine amounts of the active ingredients (i.e 0.03 wt%), the timetable necessary to achieve efficacious administration, dosage frequency.

With regard to factors three and seven, it is noted that the working examples are limited to a 0.3 wt% composition of IB-367 Such is not seen as sufficient to support the breath of the claims, wherein the scope of the claims encompasses a wider range of efficacy of the instantly claimed compounds and/or compositions. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. see In re Gardner et al. 166 USPQ 138 (CCPA 1970).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 recite the limitation " an amount effective to prevent the infection". It is not clear what constitute the metes and bounds of this amount.

The term "essentially" in claims 2, 11and 17 is a relative term, which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "about" in claims 4 and 19 is a relative term, which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Use of the abbreviation "VAP" has been noticed in claims 9, 10 and 24. Full name of said abbreviation is required when appears for the first time in the claims.

Claims 8 and 23 recite the limitation "the accessible portion of an endotracheal tube". There is insufficient antecedent basis for this limitation in the claims.

Claims 3, 5, 7, 12- 16 and 18-22 are rejected as being dependent from indefinite claims 1, 4, 10, 17 and 19.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 4, 7, 17, 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinberg et al. (WO 00/04915).

Claims are drawn to a method of preventing a respiratory infection comprising topically applying to the oral cavity of a patient a composition comprising an IB-367 peptide or a pharmaceutical acceptable salt thereof in an amount to prevent infection.

Steinberg et al. teach a method of preventing a respiratory infection comprising topically applying to the oral cavity of a patient a composition comprising an IB-367 peptide or a pharmaceutical acceptable salt thereof in an amount to prevent infection (see abstract, page 6, 9, 10, 23, 28, 36, figures 1-3 and claims specially claims 1, 20, 21, 23, 24, 25, 26 and 35-36).

Steinberg et al. teach both native and hydrochloride salt of IB-367 (claims 20-21). Steinberg et al. teach about 0.03 wt% to about 1 wt% of IB-367 (see claims 35-36). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same material structure and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-24 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kollef et al. (Phase I Safety and Microbial Kinetic Study of Oral-Topical IB-367 Rinse and Gel in Intubated Patients Receiving Mechanical Ventilation) Abstract presented in Society of Critical Care Medicine 30th International Educational & Scientific Symposium Feb 10-14, 2001.

Claims are drawn to a method of preventing a respiratory infection comprising topically applying to the oral cavity of a patient a composition comprising an IB-367 peptide or a pharmaceutical acceptable salt thereof in an amount to prevent infection.

Kollef et al. teach a method of preventing a respiratory infection comprising topically applying to the oral cavity of a patient a composition comprising an IB-367 peptide or a pharmaceutical acceptable salt thereof in an amount to prevent infection (see Methods and results. Kollef et al. teach oral decontamination using an oral rinse of IB-367 in intubated patients receiving mechanical ventilation (see title). Kollef et al. teach a method of preventing VAP. Kollef et al. do not teach explicitly about 0.03 wt% to about 0.3wt% and the individual ingredients of the oral aqueous solution mentioned in claim 10. However, the dosage and specific amounts of the solution will be inherent in the teaching of Kollef et al. Specifically in the

ongoing phase II study evaluating the efficacy of multiple dosing regimens of IB-367 rinse (see conclusions). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method and apply the composition taught by Kollef et al. to the oral cavity of patients that is at-risk of developing VAP. It would have been expected, barring evidence to the contrary, that the composition taught by Kollef et al. when administered would prevent VAP because Kollef et al. teach the same method and composition as the claimed invention. Achieving a specific dosage using the same method would be a matter of design choice based on experimental parameters. Since the office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e. that the method of prior art does not possess the same material structure and functional characteristics of the claimed method and vaccine). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Steinberg et al. US 6,025,326

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

December 5, 2003

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER